FDA Vision of Electronic Submissions

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Note: This presentation contains some ideas that we are considering for electronic submissions. Do not consider these ideas recommendations or requirements. All recommendations and requirements for providing regulatory submissions in electronic format are sent through appropriate public notice and comment procedures.

Overview

- **Where we have been**
- **Where we are**
- **Where we are going**

Where we have been
- moving toward a standard

- **1980s - CANDAs**
  - **Customized submissions**
- **1997 - PDUFA mandate**
  - **Able to accept electronic IND and NDA submissions by 2002**
- **1997 - 21 CFR part 11**
  - **Allow the submission of electronic records in lieu of paper**

Where we have been
- establishing standards

- November 1997
  - CRF and CRTs in electronic format
- February 1999
  - NDA in electronic format
- June 2000
  - CBER marketing applications in electronic format

Where we are
- Upgrading infrastructure

Electronic Document room expansion

- **Web based access to electronic submission**
- **Upgraded server**
- **Centralized processing of submissions**

Where we are
- Upgrading infrastructure

Network improvements

- **Increased bandwidth**
- **More storage**
- **Upgraded servers**
- **Improved reliability**

Where we are
- Upgrading infrastructure

Computers upgrades

- Faster processors
- Larger hard drives
- More RAM

Where we are
- Upgrading infrastructure

Monitor upgrades
- 19 and 21 inch monitors
- Flat screen monitors
- Dual monitors

Where we are
- Upgrading infrastructure

Other hardware improvements
- **Removable storage**
- **CD ROM recorders**
- **Faster printers**

Where we are
- Upgrading software tools

More powerful analysis software
- **JMP**
- **Other COTS analysis software**
- **Customized tools**

Where we are
- Training reviewers

Training

- **NDA Electronic Submission Training (NEST)**
- **NDA Electronic Data Analysis Training (NEDAT)**
- **JMP Training**
- **PDF training**

Where we are
- Upgrading document management

Internal document archiving
- **PDF**
- **Documentum**

Where we are
- Improving internal communication

Agency electronic submission working group

- **CDER, CBER, CDRH, CVM, CFSAN**
- **General considerations guidance**
- **Electronic submission initiatives in each center**

Where we are
- Submission increasing

Statistics
1998 – average 6 per month
1999 – average 19 per month
2000 – average 38 per month

Where we are going
- Preparing for the paperless environment

- **Continued training and education (internal and external)**
- **Scale up processes for total electronic submissions**
- **Guidance for electronic submissions**
- **Regulations for electronic submissions**

Where we are going
- Improving processes

Electronic transmission of data

- **EDI gateway**
  - **Postmarketing safety reports**
- **Other electronic transactions**
- **Clinical trials data bank**
- **Investigator information**
- **Clinical trials annual report summary**
- **Drug registration and listing**

Where we are going
- Improving processes

Reduce manual processing of data

- Structured data submissions
  - Administrative
  - Study data
- Data entry directly into databases
- Review specific analysis tools

Where we are going
- Improving data management

Structured study data submissions

- **Postmarketing safety reports**
- **Clinical trials data bank**
  - **Protocol demographics**
  - **Monitor drug development**
  - **Manage resources**
- **Investigator information**

Where we are going
- Improving data management

More structured study data submissions

- **PK and Bioequivalence data**
- **Carcinogenicity data**
- **Clinical safety studies**
  - **Standard set of safety data**
- **Animal toxicology**
  - **Standard set of safety data**

Where we are going
- Guidance for electronic submissions

Procedures

- **Prepare draft guidance**
- **Public comments**
- **Final guidance**
- **Place submission on the docket for voluntary replacement of paper**

Where we are going
- Paperless for other submission

- **Postmarketing safety reports**
- **IND electronic submission**
- **NDA annual report**
- **Abbreviated NDAs**
- **Drug advertising and promotional labeling**
- **DMF**

Where we are going
- Moving to paperless environment

Benefits of electronic submissions

- **Increased review efficiency**
- **Increased processing efficiency**
- **Improved management of resources**
- **Centralized processes**
- **Improved collection of admin data**

Where we are going
- Regulations for electronic submissions

Disadvantages of dual paper and electronic system

- **Reduces benefits of paperless submission**
- **Increases costs**

Where we are going
- Regulations for electronic submissions

Requiring electronic submissions

- **Labeling**
- **Postmarketing safety reports**
- **Drug registration and listing**
- **Clinical trials data bank**

Where we are going
- Regulations for electronic submissions

Requiring electronic submissions

- Clinical safety and efficacy data
- Animal toxicology data
- Clinical investigator information
- Drug master files
- IND
- NDA

Other talks on electronic submissions

- **Experience with electronic NDAs**
- **Clinical data in electronic submissions**
- **Future IT initiatives - Electronic IND**
- **Safety data standards**

Follow our progress:

www.fda.gov/cder/regulatory/ersr/default.htm

Questions:

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